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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,343	02/18/2004	Hugo Quiroz-Mercado	KARAG-009A	9228

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/781,343	QUIROZ-MERCADO ET AL.
	Examiner	Art Unit
	Leslie R. Deak	3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *22-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10,11,16 and 19-21* is/are rejected.

7)☒ Claim(s) *9,12-15,17 and 18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/25/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on 2 October 2006 is acknowledged.

2. Claims 22-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2 October 2006.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1-2 recite the steps of creating a passageway between the posterior chamber of the eye and one of a) the optic nerve or b) subarachnoidal space by implanting a tubular shunt. Claim 20, which depends from claim 2, recites that the shunt bypasses the posterior chamber of the eye. The specification, figures, and claims fail to explain how a passageway may be created between the posterior chamber and another

portion of the eye if the device creating the passageway bypasses the posterior chamber. Therefore, the claim is not enabled by the specification.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-2 recite the steps of creating a passageway between the posterior chamber of the eye and one of a) the optic nerve or b) subarachnoidal space by implanting a tubular shunt. Claim 20, which depends from claim 2, recites that the shunt bypasses the posterior chamber of the eye. The specification, figures, and claims fail to explain how a passageway may be created between the posterior chamber and another portion of the eye if the device creating the passageway bypasses the posterior chamber. Examiner cannot reasonably determine the metes and bounds of the claim, since the limitations in the claims appear to be mutually exclusive.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-7, and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,402,681 to Haas et al.

In the specification and figures, Haas discloses the method as claimed by applicant. With regard to claims 1-2, Haas discloses a shunt 28 and a method for implantation that creates a passageway between the posterior chamber 20 of the eye and the outside of the eye, which constitutes the subarachnoid space (see FIG 1). Fluid from the posterior chamber enters the shunt 28 at penetrant end 50, travels through stem 46, and drains from the shunt into the subarachnoid space via perforations 44 on housing means or flange 30 (see FIGS 1-2, column 6).

Haas does not disclose specifically that the passageway connects to the subarachnoid space, but illustrates that the outlet of the shunt is disposed outside the sclera 22 of the eye, as illustrated by applicant in FIG 2C. It is the position of the examiner that the area outside the sclera of the corresponds to applicant's recitation of the subarachnoid space. As such, the Haas device and method performs as disclosed and claimed by applicant, meeting the limitations of the claims.

With regard to claims 3-5, 7, 10, and 19-21, applicant claims the structure of a device used in the claimed method. It has been held that in order to be entitled to patentable weight in method claims, the recited structural limitations therein must affect the method in a manipulative sense and not to amount to the mere claiming of a use of a particular structure. See *Ex Parte Pfeiffer*, 135 USPQ 31. It is the position of the examiner that the recited structural limitations do not affect the method as claimed by applicant, rendering claims 3-5, 7, and 20-21 anticipated by the Haas reference.

Notwithstanding the failure of the limitations to further limit the claimed method, Haas discloses several components recited by applicant. With regard to claims 5, 7, and 10, Haas discloses that the shunt comprises a housing or flange 30, a dome 40, corresponding to applicant's shielding member, and a a tube 46 with a distal tip 50 that penetrates the retina and choroids sclera (see column 6, lines 1-28)

With regard to claim 6, applicant claims a valve as a structural feature of the shunt used in the claimed method and the movement of fluid through the valve. However, applicant's recitation that the claimed valve is "operative" to perform a particular function means that in order to anticipate the claimed valve, the prior art need only be able to perform the claimed function. In the instant case, Haas discloses that shunt 28 comprises a unidirectional slit valve 52 that opens upon a particular fluid pressure (see column 6, line 65 to column 7, line 9), thereby meeting the limitations of the claim.

With regard to claim 8, Haas discloses that dome 40 comprises openings 44, creating a semipermeable membrane. Together with the unidirectional valve 52, the perforated dome permits fluid flow out of the distal end of the tube but prevents debris from entering the tube at the distal end, thereby meeting the limitations of the claims.

With regard to claim 16, Haas discloses that the shunt comprises a proximal opening 50 that accepts fluid from the posterior chamber of the eye, allowing fluid to flow through tube 46 and drain through distal end 44 to the subarachnoid space (see column 6, FIG 1).

9. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by US 5,171,213 to Price, Jr.

In the specification and figures, Price discloses a method for lowering intraocular pressure including the steps of inserting a tube (thereby creating a passageway) into the posterior chamber of the eye and allowing fluid to drain to the exterior of the eye (illustrated by applicant as the subarachnoidal space) in conjunction with a vitrectomy (see FIG 1b, column 4, lines 3-40).

Price illustrates that the outlet of the shunt is disposed outside the sclera of the eye 10, corresponding to the illustration by applicant in FIG 2C. In light of applicant's illustration, it is the position of the examiner that the area outside the sclera of the eye (as illustrated by both Haas and applicant) corresponds to applicant's recitation of the subarachnoid space. As such, the Price device and method performs as disclosed and claimed by applicant, meeting the limitations of the claims.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 3-4 are rejected, in the alternative, under 35 U.S.C. 103(a) as being unpatentable over US 4,402,681 to Haas in view of US 3,788,327 to Donowitz et al.

In the specification and figures, Haas discloses the method substantially as claimed by applicant (see rejection above) with the exception of some of the structural limitations drawn to the shunt used in the claimed method. Applicant's limitations drawn to the structure of the shunt are not considered by the examiner to affect the function of the shunt. Assuming, however, that these structural limitations do affect the claimed method, such limitations are obvious variations of the prior art, as set forth below.

With regard to claims 3 and 4, Haas fails to disclose that the shunt comprises a tissue engaging member to deter unwanted movement or subsequent retraction of the shunt. However, Donowitz discloses an ocular shunt with two ends and barbs 46 that function as tissue engaging members to deter retraction (which is an unwanted movement) of the shunt (See FIG 4, column 2, lines 51-63). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add barbs as disclosed by Donowitz to the shunt disclosed by Haas in order to maintain the shunt in position, as taught by Donowitz.

Allowable Subject Matter

12. Claims 9, 12-15, 17-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest the method as claimed by applicant.

With regard to claims 9 and 15, the prior art fails to disclose or suggest the steps of claim 1 in combination with the formation of an opening in the pars plana, optic nerve, or lamina cribosa. The best prior art of record, US 6,863,073 to D'Amico et al, discloses the step of creating an opening in the lamina cribosa to treat central retinal vein occlusion, but does not disclose or suggest any reason for combining the disclosed method with a procedure for draining fluid from the posterior chamber of the eye.

With regard to claims 12-14, the prior art fails to disclose or suggest the combination of the steps of claim 1 in combination with vitreal liquefaction with removal of fluid from the posterior chamber of the eye, along with the other steps and limitations of the claims. The best prior art of record, US 6,610,292 to Karageozian et al, discloses the step of liquefaction of the vitreous to treat various eye disorders, but provides no disclosure or suggestion to combine the liquefaction with fluid removal from the posterior chamber of the eye.

With regard to claim 17-18, the prior art fails to disclose or suggest the staps of claim 1 in combination with the method of placing the shunt as claimed by applicant, in particular, locating the shunt adjacent to the lamina cribosa and extending into the optic nerve, along with the other steps and limitations of the claims.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. US 4,490,351 Clark, Jr

i. Methods of treating eye by replacing vitreous

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
29 November 2006